



UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/830,986

05/03/01

BERNKOP-SCHNURCH

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030560-056

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HM12/0925

BURNS DOANE SWECKER & MATHIS
PO BOX 1404
ALEXANDRIA VA 22313-1404

EXAMINER

WILLIS, M	
ART UNIT	PAPER NUMBER

1619
DATE MAILED:

09/25/01

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Applicati n N .

09/830,986

Examiner

Michael A. Willis

Applicant(s)

BERNKOP-SCHNURCH,
ANDREAS

Art Unit

1619

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 June 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 28-99 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 28-99 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claims 1 and 28-99 are pending.

Duplicate Claims

1. Applicant is advised that should claims be found allowable, duplicate claims will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). The pairs of duplicate claims are as follows: 30 and 74, 50 and 87, 53 and 89, 54 and 90, 55 and 91, 58 and 92, 59 and 94, 60 and 95, and 62 and 96.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 30, 48-55, 62, 71, 72, 74, 75, 77-91, 96, and 99 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claims 30, 50, 62, 72, 74, 75, 82, 96, and 99 are vague and unclear due to the term "derivatives". The metes and bounds of the claim cannot be determined due to the term.

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5. Claims 48, 50, 53, 54, 55, 87, 89, 90, and 91 are vague and unclear due to the phrase "an effective amount". The effect desired by the amount of the pharmaceutical composition to be administered is unclear, so it is not possible to determine the amount required to be effective.
6. Claims 53 and 89 are rejected due to the phrase "a method of treating an individual in need of a treatment". The circular nature of the phrase makes it unclear which individuals are specified in the claim.
7. Claim 53 is rejected due to lack of antecedent basis for "the active ingredient" in line 1 of the claim.
8. Claim 71 is rejected due to lack of antecedent basis for "said drug".
9. Claim 72 appears to have a typographical error in the phrase "a polymer as set form in claim 30".
10. Any remaining claims are rejected for depending from indefinite base claims.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1, and 28-32 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Constancis et al (US Pat. 5,496,872). Constancis discloses compounds including polysulfides with recurring units of succinic acid and cysteine (see col. 4, lines

44-49). The polymers described serve as a base for other adhesive compounds, including chitosan (see col. 4, line 49 through col. 5, line 25).

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

15. Claims 1 and 28-99 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bernkop-Schnurch et al (International Journal of Pharmaceutics, vol. 157, 1997, pp. 17-25; International Journal of Pharmaceutics, vol. 146, 1997, pp. 247-254) in view of Constancis et al (US Pat. 5,646,239).

16. Bernkop-Schnurch teaches a drug delivery system protecting from enzymatic degradation. In one reference, a mucoadhesive polymer is conjugated with an active agent that inhibits α -chymotrypsin (see vol. 146, page 247, abstract). Additionally, Bernkop-Schnurch teaches the preparation and use of a chitosan-antipain conjugate

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that is mucoadhesive for the delivery of insulin (see vol. 157, page 17, abstract). The mucoadhesive properties of polymer conjugates are taught (see vol. 146, page 251, section 3.3). The references lack thiol groups.

17. Constancis teaches the modification of biomaterials with thiolated compounds, including polysulfides (see col. 3, line 64 through col. 4, line 56). Cross-linking is carried out with cysteine (see col. 4, lines 49-56). The thiol groups are added to biomaterials such as chitosan (see col. 5, lines 5-23). The modified biomaterials are used as adhesives for binding between biological material and implanted biomaterial (see col. 5, lines 24-30).

18. It would have been obvious to one of ordinary skill at the time the invention was made to have modified the compositions and methods of Bernkop-Schnurch by the addition of thiol groups as taught by Constancis in order to benefit from the improved adhesive properties for binding between biological material and implanted biomaterial, as taught by Constancis.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael A. Willis whose telephone number is (703) 305-1679. The examiner can normally be reached on Mon. to Fri. from 9 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diana L. Dudash can be reached on (703) 308-2328. The fax phone numbers for the organization where this application or proceeding is assigned are (703)

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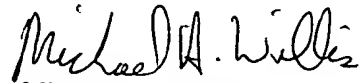
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308-2742 for regular communications and (703) 308-2742 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Michael Hartley
Primary Examiner


Michael A. Willis, Ph.D.
Examiner
Art Unit 1619

September 24, 2001


DANA DUDASH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600